prescription drug sales after application of the percentage adjustment table in section 9008(b)(2) (relating to annual sales less than $400,000,001). See §51.5(a)(3).

(m) *Sales year*. The term *sales year* means the second calendar year preceding the fee year. Thus, for example, for the fee year of 2014, the sales year is 2012.

[T.D. 9684, 79 FR 43639, July 28, 2014]

§51.2T Explanation of terms (temporary).

(a) Through (e)(2) [Reserved]. For further guidance see §51.2(a) through (e)(2).

(3) *Controlled Group*. The term *controlled group* means a group of two or more persons, including at least one person that is a covered entity, that is treated as a single employer under section 52(a), 52(b), 414(m), or 414(o).

(e)(4) through (m) [Reserved]. For further guidance see §51.2(e)(4) through (m).

[T.D. 9684, 79 FR 43639, July 28, 2014]

§51.3 Information requested from covered entities.

(a) *In general*. Annually, each covered entity may submit a completed Form 8947, ''Report of Branded Prescription Drug Information,'' in accordance with the instructions for the form. Generally, the form solicits information from covered entities on NDCs, orphan drugs, designated entities, rebates, and other information specified by the form or its instructions.

(b) *Due date*. Form 8947 must be filed by the date prescribed in guidance in the Internal Revenue Bulletin.

[T.D. 9684, 79 FR 43641, July 28, 2014]

§51.4 Information provided by the agencies.

(a) *In general*. For each sales year, the IRS will compile a list of branded prescription drugs by NDC using the data submitted on Forms 8947 and in error reports submitted as part of the dispute resolution process (described in §51.7) and, after applying appropriate due diligence, will provide this list to the Agencies. The Agencies will provide data to the IRS on branded prescription drug sales that occurred during the sales year by Program and NDC. The Agencies will provide data for use in preparing the preliminary fee calculation (described in §§51.5 and 51.6) and may revise or supplement that data following review of error reports submitted as part of the dispute resolution process. The calculation methodology for calculating the sales amounts for each Program, including any reasonable estimation techniques and assumptions that the Agencies expect to use, is described in this section.

(b) *Medicare Part D*—(1) *In general*. CMS will determine branded prescription drug sales under Medicare Part D by aggregating the ingredient cost reported in the ''Ingredient Cost Paid'' field on the Prescription Drug Event (PDE) records at the NDC level, reduced by discounts, rebates, and other price concessions provided by the covered entity, for each sales year. CMS will only include PDE data that Part D sponsors have submitted by the PDE submission deadline (within 6 months after the end of the sales year) and that CMS has approved for inclusion in the Part D payment reconciliation.

(2) *Discounts, rebates, and other price concessions*—(i) *In general*. For purposes of paragraph (b)(1) of this section, the term *discounts, rebates, and other price concessions* means:

(A) Any direct and indirect remuneration (DIR) (within the meaning of paragraph (b)(2)(ii) of this section), which includes any DIR reported on the PDE records at the point of sale and any DIR reported on a Detailed DIR Report (within the meaning of a paragraph (b)(2)(iii) of this section); and

(B) Any coverage gap discount amount (within the meaning of paragraph (b)(2)(iv) of this section).

(ii) *Direct and indirect remuneration*. For purposes of paragraph (b)(2)(i)(A) of this section, the term *direct and indirect remuneration* (DIR) has the same meaning as found in the definition of *actually paid* in 42 CFR 423.308.

(iii) *Detailed DIR Report*. For purposes of paragraph (b)(2)(i)(A) of this section, the term *Detailed DIR Report* means the report containing any DIR (within the meaning of paragraph (b)(2)(ii) of this section) that is collected yearly from Part D sponsors at the NDC level.